AUG 1 2 2011

2011 K110627

5. 510(k) Summary

General Information

Date Compiled	March 3, 2011
Classification	Class II, 21 CFR § 880.5970, Percutaneous, implanted, long-term intravascular catheter, Product code LJS
Trade Name	NexSite 9Fr Dual Lumen Critical Care Central Venous Catheter
Submitter	Marvao Medical Devices, Ltd. GMIT Innovation in Business Centre, Dublin Road Galway, Ireland
Contact	Marybeth Gamber Boston Biomedical Associates Phone: (508) 351-8632 Fax: (508) 351-8637

Intended Use

The NexSite 9Fr Dual Lumen Critical Care Central Venous Catheter is indicated for long-term access to the Central Venous System. It is designed for administering IV fluids, blood products, drugs, and parenteral nutrition as well as blood withdrawal and power injection of contrast media. The maximum pressure of power injectors used with the NexSite device may not exceed 300psi.

Predicate Devices

PowerHickman® Central Venous Catheter Manufactured by Bard Access Systems	K061179
Medcomp® PRO-LINE™ CT Power Injectable CVC Manufactured by Medcomp®	K053345

Device Description

The NexSite 9Fr Dual Lumen Catheter is a long-term central venous catheter. The polyurethane Catheter is 55.5cm in length, and has a Dacron cuff distal to the bifurcation hub. A Polyurethane/Dacron Port supplied with the Catheter is implanted subcutaneously, and is intended to minimize Catheter movement. The Catheter and Port are packaged with accessories that are used to facilitate Catheter and Port insertion.

Materials

The NexSite Catheter assembly is comprised of materials that are commonly used in medical device applications. Materials for the Catheter and Port include polyurethane, polycarbonate and Dacron.

Testing

In vitro testing was performed on the NexSite 9Fr Dual Lumen Critical Care Central Venous Catheter to assure reliable design and performance in accordance with ISO 10555-1 and ISO 10555-3. The non-clinical tests performed by the company include visual and dimensional, catheter leakage, catheter joint strength, catheter pressure, radiopacity, corrosion resistance, and catheter high pressure injection. The test results demonstrate that the NexSite Catheter meets the requirements in the applicable standards and specifications, and is substantially equivalent to legally marketed predicate devices.

In vivo testing was also performed to demonstrate that the device would perform as intended. Clinical studies were not deemed necessary since *in vivo* and *in vitro* testing were sufficient to demonstrate safety and effectiveness by way of comparison to a legally marketed predicate device.

Guidance

The FDA Guidance on Premarket Notification [(510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, dated 3/16/95, was utilized in order to meet the FDA requirements for content and organization of this submission.

Summary of Substantial Equivalence

Marvao Medical believes the NexSite 9Fr Dual Lumen Critical Care Central Venous Catheter is substantially equivalent to the predicate products. The intended use, method of operation, methods of construction and materials used, are either identical or substantially equivalent to existing legally marketed predicate products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Marvao Medical Devices, Limited
C/O Ms. Marybeth Gamber
Principal Regulatory Consultant
Boston Biomedical Associates
368 West Main Street, Suite 7
Northboro, Massachusetts 01532

AUG 12 2011

Re: K110627
Trade/Device Name: NexSite 9Fr Dual Lumen Critical Care Central Venous Catheter
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted long-term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: July 14, 2011
Received: July 15, 2011

Dear Ms. Gamber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

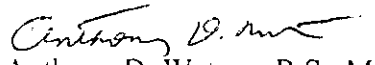
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known):	This application
Device Name:	NexSite 9Fr Dual Lumen Critical Care Central Venous Catheter
Indications for Use:	The NexSite 9Fr Dual Lumen Critical Care Central Venous Catheter is indicated for long-term access to the Central Venous System. It is designed for administering IV fluids, blood products, drugs, and parenteral nutrition as well as blood withdrawal and power injection of contrast media. The maximum pressure of power injectors used with the NexSite device may not exceed 300psi.

Prescription Use _X_ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (Per 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

8/12/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110627